


# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference B-15300 PCT	<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/B2005/000506	International filing date (day/month/year) 25.02.2005	Priority date (day/month/year) 26.02.2004	
International Patent Classification (IPC) or national classification and IPC C08B37/00			
Applicant PHARMA MEDICAL LIMITED et al			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand  05.09.2005		Date of completion of this report  18.01.2006	
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Gerber, M  Telephone No. +49 89 2399-	



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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language ;  
which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-18 as originally filed

**Claims, Numbers**

1-36 as originally filed

**Drawings, Sheets**

1/7-7/7 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	1-36
	No: Claims	
Inventive step (IS)	Yes: Claims	1-36
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	22-36

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**10/590625**

**IAP9 Rec'd PCT/PTO 24 AUG 2006**

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**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

- D1:** CARNEY S L: "EFFECT OF DIACETYL RHEIN ON THE DEVELOPMENT OF EXPERIMENTAL OSTEOARTHRITIS A BIOCHEMICAL INVESTIGATION" December 1996, OSTEOARTHRITIS AND CARTILAGE, BAILLIERE TINDALL, LONDON, GB, PAGE(S) 251-261 , XP001056066 ISSN: 1063-4584
- D2:** BARBUCCI R ET AL: "Hyaluronic acid hydrogel in the treatment of osteoarthritis" December 2002, BIOMATERIALS, ELSEVIER SCIENCE PUBLISHERS BV., BARKING, GB, PAGE(S) 4503-4513 , XP004377521 ISSN: 0142-9612

**1. Novelty**

D1 is concerned with the use of rhein in the treatment of joint disorders and D2 deals with the implementation of hyaluronic acid in the treatment of osteoarthritis.

None of these documents discloses the esterification of hyaluronic acid with rhein.

The subject-matter of claims 1-36 is novel over the cited state of the art (Article 33(2) PCT).

**2. Inventive step**

The hyaluronic acid esterified with rhein exhibits an improved pharmacological activity than hyaluronic acid or rhein alone (see page 17, line 14 - page 18, line 2, as well as figures 4 and 5).

The technical problem underlying the present application is the provision of a compound based on hyaluronic acid with improved pharmacological activity.

None of the cited documents cited alone or in combination would have prompted the

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skilled person seeking to solve the above-mentioned technical problem to esterify hyaluronic acid with rhein.

The subject-matter of claims 1-36 is therefore considered inventive (Article 33(3) PCT).

**3. Industrial applicability**

**3.1.** The subject-matter of present claims 1-21 appears to comply with the requirements of industrial applicability as stipulated in Article 33(4) PCT.

**3.2.** Claims 22-36 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).